UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/573,569	12/14/95	MAASSAB	H

HM22/0829

ANTIONETTE F KONSKI
BAKER & MCKENZIE
660 HANSEN WAY
PALO ALTO CA 94304-1018

EXAMINER	
PARKIN, J	
ART UNIT	**PAPER NUMBER**
1648	27

DATE MAILED: 08/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/573,569	Applic...t(s) Maassab et al.
	Examiner Jeffrey S. Parkin, Ph.D.	Group Art Unit 1648

X Responsive to communication(s) filed on *17 Jul 2000*.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) *1, 4, 5, 7, 8, 12, 19, 20, 22, 23, and 25-27* is/are pending in the application.

Of the above, claim(s) *1, 4, 5, 7, 8, 19, 20, 22, 25, and 26* is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

X Claim(s) *12, 23, and 27* is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Detailed Office Action

Continued Prosecution Application

1. The request filed on 17 July, 2000, for a Continued Prosecution Application (CPA) under 37 C.F.R. § 1.53(d) based on parent Application Serial No. 08/573,569 is acceptable and a CPA has been established.

Status of the Claims

2. The aforementioned CPA request did not contain any accompanying amendments or arguments. Applicants are reminded that claims 1, 4, 5, 7, 8, 19, 20, 22, 25, and 26 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 9. Claims 12, 23, and 27 are currently under examination.

35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 12 and 27 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Cox *et al.* (1988), for the reasons of record clearly set forth in Paper Nos. 11, 17, and 24. It is noted that Applicants did not file any arguments with the response. As previously set forth, this teaching discloses a vaccine comprising an influenza A viral reassortant comprising nucleotides encoding

the HA (wild-type), NA (wild-type), PB1 (cold-adapted), PA (cold-adapted), M (cold-adapted), and PB2 (including SEQ ID NO.: 15) polypeptides. These nucleotide sequences were linked in such a manner as to allow packaging of the reassorted polynucleotides into the virion.

35 U.S.C. § 103(a)

5. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

7. Claims 12, 23, and 27 stand rejected under 35 U.S.C. § 103(a) as

being unpatentable over Cox et al. (1988) in view of Maassab *et al.* (1982), for reasons of record previously set forth in Paper Nos. 17 and 24. Applicants' response did not contain any arguments. As previously set forth, Cox *et al.* (1988) provides methods for the production of live attenuated influenza A vaccines by genetic reassortment with a cold-adapted mutant. Reassortant viruses containing HA and NA genes form strains H1N1 and H3N2 were disclosed. This teaching additionally discloses that five or six internal genes were derived from the ca A/Ann Arbor/6/60 parental strain. Maassab et al. (1982) teaches that reassortants comprising six genes derived from one strain and two surface proteins derived from the wild-type parental strain were generated and that these viruses were attenuated and genetically stable (see abstract). The intranasal inoculation of the a vaccine composition comprising this strain was also described. This reassortant was unable to replicate in lung tissue and grew to low titers in the nasal turbinates as compared to wild-type. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to produce a live Influenza A vaccine using cold-adapted parental strains and to incorporated these properties into a clinically relevant strain by mating and reassortant technology. One of ordinary skill in the art would have a reasonable expectation of succeeding because Cox and colleagues provide those mutations that are responsible for the cold-adapted phenotype. One of ordinary skill in the art could incorporate these changes into a helper virus to produce a safe, attenuated, vaccine strain.

Correspondence

8. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648.**

9. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

10. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

25 August, 2000